



K/112099

FEB - 3 2012

510(k) Summary

This summary of information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

Submitter Information

510(k) owner's name: Contour Healer, LLC.

Address: 1117 Ditchley Road, Virginia Beach, VA 23451 USA

Phone number: 757 288 6671

Fax number: 757-428-3470

Name of contact person: Allen Hardin White, III, D.D.S.

Date of Summary: September 2011

Device Trade Name: Contour Healer Temporary Abutment

Device Classification Name: Endosseous Dental Abutment

Classification: Class II, 21 CFR 872.3630; Product Code NHA

Legally marketed device to which equivalence is claimed: Zimmer Dental Plastic Temporary Abutment [K092377]

Device Description

The Contour Healer, LLC product line includes pre-manufactured dental abutments intended to serve as a temporary dental prosthesis during the healing process until a permanent crown is fabricated. The abutment is made of PEEK Classix and is directly connected to the endosseous dental abutment by a stainless steel screw.

These abutments have biconvex domes to mimic emergence of the original tooth morphology, and therefore provide for a more esthetic gingival contour during the restorative phase. The abutments come in several abutment- to-implant diameters. The abutments are intended for single-use not to exceed ninety days. At the end of the treatment period, the temporary abutment is to be removed by clinician and the permanent crown is installed.

Indications for Use

The Contour Healer Temporary Abutment is intended for use with a root-form endosseous dental abutment to aid in prosthetic rehabilitation. The abutment is a provisional restoration that aids in creating an esthetic emergence through the gingiva during the healing period. The device is for use by dental professionals for single restorations in adults. The device is for single-use only and may not be re-processed.

These abutments are designed to work with the following implant systems:

Zimmer [Screw-Vent Dental Implant System]

Nobel Biocare [Replace HA Coated Implant, Replace TiUnite Endosseous Implant, Nobel Biocare Endosseous Implants, and Groovy Implants]

BioHorizons [BioHorizons Tapered Internal Implant System].

Testing

First article inspections are done on each molding run to ensure that the devices meet all dimensional specifications. Routine inspections are done on 100% of the Contour Healer devices to ensure that each temporary abutment meets design specifications. This finishing and inspection process includes hand polishing of each piece, visual inspection of each piece for flash and debris, a check for correct fit [passive] of temporary abutment into the corresponding implant analog [to ensure that each piece will fit into the corresponding implant], and a check for correct screw fit into the temporary abutment, before final packaging of each piece.

The stainless screw used with each model of the temporary dental abutment are purchased to specification from the manufacturer and are received by Contour Healer with certification testing results for chemical analysis and 11 different performance specifications per standards.

Biocompatibility of the finished, sterilized temporary abutments was demonstrated per ISO-10993-1, -5, -10, and -12 for cytotoxicity, irritation, delayed contact hypersensitivity, and acute systemic toxicity.

Formal clinical studies were not conducted on the device since [per the FDA Guidance document "Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" issued on May 12, 2004]: 1] the material formulation is identical to a device previously cleared for this intended use, 2] the design is similar to the design of the predicate devices, 3] the lengths of each of the Contour Healer temporary dental abutment models are greater than 7 mm, 4] the implant diameters for each of the models are all greater than 3.25 mm, 5] the angulation of the accompanying or recommended implant abutment is less than 30°, 6] there is no new technology required for the manufacture or the deployment of the device, and 7] the indications for use are identical to those of the previously cleared devices of the same type.

However, formal design validation studies have been done on the Contour Healer devices by several dental professionals to confirm the safety and efficacy of the device design for the intended use, and to ensure that the product labeling is clear and appropriate for the indications for use of the temporary abutment. No unexpected or device-related adverse events or complications were found in these studies.

Summary Comparison Table of New Device to Predicate Device

Parameter	Device	Predicate Device
Device Name	Contour Healer	Plastic Temporary Abutment
Company Name	Contour Healer, LLC	Zimmer Dental, Inc.
510(k) #	TBD	K092377
Class	II	Same
21 CFR number	872.3630	Same
21 CFR category	Endosseous dental abutment [temporary]	Same
Code	NHA	Same

Parameter	Device	Predicate Device
Description	Abutment is a plastic post with a predefined junction and abutment core. The plastic stem of the abutment engages the internal aspects of the endosseous implant and is secured with a separate retaining screw. The abutment is packaged with a stainless steel screw for retaining the temporary healing abutment to the endosseous implant. The abutments are provided in straight versions only.	Abutment is a plastic post with a predefined margin and abutment cone; available in multiple cuff heights and straight and angled cone variations. The plastic hex of the abutment engages the internal hex of the <i>Tapered Screw-Vent</i> or <i>Screw-Vent</i> Implant and is secured with a separate retaining screw. Abutment is packaged with two screws, a long processing screw for fabricating a screw-retained temporary restoration and a short retaining screw for fabricating a cement-retained restoration
Use Features	Pre-manufactured prosthetic component; screw-retained	Same; cement-retained or screw-retained
Ancillary components	Not applicable; for attachment to endosseous permanent implant	Same
Intended Use	To be used in conjunction with an endosseous dental implant fixture to aid in prosthetic rehabilitation	Same
Indications for use	A provisional restoration that aids in creating an esthetic emergence through the gingiva during the healing period The device is for use by dental professionals for single restorations in adults. The device is for single-use only and may not be re-processed.	To fabricate and support provisional restorations that aid in creating and esthetic emergence through the gingiva during the healing period, before final restoration Single- or multi-unit restorations
End User	Dentist, periodontist, oral surgeon	Same
Frequency of Use	Single use	Same
Method of Use	Temporary prosthesis; 90 days maximum	Same; 180 days maximum

Parameter	Device	Predicate Device
Contraindications	Not to be used as a final abutment; not to be used "in occlusion"; not to be used as a "cast-to" abutment	Same
Standards met	ISO 10993; ISO 14971	ISO 10993
Abutment Material	PEEK Classix; polyetheretherketone	Same
Screw material	Stainless steel	Titanium alloy
Design [style, size]	Contoured shaped with interfaces to match endosseous implants with various platform size [abutment to implant diameters of 5.0, 4.3, 4.5, and 5.7mm], in straight versions only	Straight and angled versions, with interfaces to match three diameters of tapered screw-vent implants [3.5, 4.5, and 5.7 mm], 1 mm and 4 mm cuff height options
Screw geometry	Internal hex with friction fit	Internal hex [anti-rotational] with friction fit
Sterility	Non-sterile; intended for autoclave sterilization by end user	Sterilized by gamma irradiation, but instructions for autoclaving by the end user are provided
Packaging	Round plastic vial with screw cap	Sealed Tyvek blister packs

Device Comparison Statement

The new device and the predicate devices are temporary dental abutments consisting of a plastic post with a predefined junction and abutment core. In both devices the plastic stem of the abutment engages the internal aspects of the endosseous implant and is secured with a separate stainless steel retaining screw.

The Contour Healer differs from the predicate device in that the shape more closely mimics the shape of the permanent crown as opposed to a straight cylinder. The most difficult stage of implant surgery is to manage the peri-implant soft tissue contour. Shape and form of the peri-implant tissues are equally as important as other important factors such as bone quantity/quality, primary stability, and bone to implant contact. The Contour Healer abutment serves as a template to easily shape the soft tissue to proper form and allows the natural contours to be maintained without compromising the stability of the newly placed implant. The restorative phase is easier as the tissues are ready to be impressed along with the impression coping on the implant.

The Contour Healer product for the management of the peri-implant soft tissue contour is substantially equivalent to the previously-cleared device, with the same indications for use, abutment material, and similar design and technological characteristics and therefore does not raise any new questions for safety. Contour Healer has further supported the safety and the efficacy of this product by user design validation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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Virginia Beach, Virginia 23451

FEB - 3 2012

Re: K112099
Trade/Device Name: Contour Healer Temporary Dental Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 9, 2012
Received: January 19, 2012

Dear Dr. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

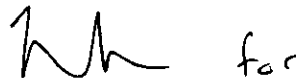
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'A. Watson' or similar, followed by the word 'for'.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112099

Device Name: Contour Healer Temporary Dental Abutment

Indications for Use:

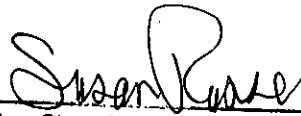
The Contour Healer Temporary Abutment is intended for use with a root-form endosseous dental abutment to aid in prosthetic rehabilitation. The abutment is a provisional restoration that aids in creating an esthetic emergence through the gingiva during the healing period. The device is for use by dental professionals for single restorations in adults. The device is for single-use only and may not be re-processed.

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112099

Prescription Use X
(Part 21 CFR 801 Subpart D)